Approvals & Updates

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New Drug Approvals

Filspari (sparsentan)

Indication: Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN)

Mechanism of Action: Endothelin (ERA) and angiotensin II receptor antagonist (ARB)

Dosage Form(s): Oral tablets

Comments: Filspari is FDA-approved for treating adults with proteinuria (urine protein-to-creatine ratio (UPCR) ≥ 1.5g/g) and primary IgAN who are at an increased risk of rapid disease progression. The recommended dose of Filspari is 200mg orally swallowed whole with water once daily prior to the morning or evening meal for 14 days. Then it is recommended to increase the dose of Filspari to 400mg once daily as tolerated. Filspari is contraindicated in pregnancy and with concomitant administration of ARBs, ERAs, or aliskiren. Filspari has a boxed warning for hepatotoxicity and embryo-fetal toxicity. Due to these associated risks, Filspari is only available through the Risk Evaluation and Mitigation Strategies (REMS) program. The labeled warnings and precautions associated with Filspari are hepatotoxicity, embryo-fetal toxicity, hypotension, acute kidney injury, hyperkalemia, and fluid retention. An extensive list of drug-drug interactions is associated with Filspari. Avoid the concomitant use of Filspari with strong CYP3A inhibitors and monitor for adverse reactions if used with moderate CYP3A inhibitors due to the increased exposure of Filspari. Avoid the concomitant use of Filspari with strong CYP3A inducers and acid reducing agents due to decreased Filspari exposure. Frequent monitoring of serum potassium should occur if Filspari is concomitantly used with drugs that increase serum potassium due to the increased risk of hyperkalemia. Use of Filspari is contraindicated with renin-angiotensin system inhibitors and ERAs due to the increased risk of hypotension and hyperkalemia. Avoid the use of antacids within 2 hours before or after Filspari. Signs of worsening renal function and increased risk of injury should be monitored if Filspari is concurrently used with NSAIDs and COX-2 inhibitors. Due to decreased exposure the efficacy of concurrently administered substrates (CYP2B6, 2C9, and 2C19) should be monitored. Avoid the concomitant use with sensitive P-gp and BCRP substrates. The most common adverse reactions (≥5%) reported with Filspari are peripheral edema, hypotension, orthostatic hypotension, dizziness, hyperkalemia, and anemia.

Jesduvroq (daprodustat)

Indication: Anemia due to chronic kidney disease (CKD) in patients on dialysis

Mechanism of Action: Hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor

Dosage Form(s): Oral tablets

Comments: Jesduvroq is FDA-approved for treating adults with anemia and CKD who have been on dialysis for ≥ four months. Jesduvroq has limited uses and has not been demonstrated to improve quality of life, fatigue, or patient well-being. Jesduvroq should not be used for patients not on dialysis or as a transfusion substitute for immediate correction of anemia. The recommended starting dose of Jesduvroq is based on pre-treatment hemoglobin level, liver function tests, and concomitant medications. Jesduvroq 1mg, 2mg, or 4mg is administered with or without food orally once daily for adults on dialysis but not receiving an erythropoiesis-stimulating agent (ESA). Jesduvroq 4mg, 6mg, 8mg, or 12mg once daily is the recommended starting dose for adults on dialysis and switching over from an ESA agent. Jesduvroq has a boxed warning for increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. Jesduvroq is contraindicated in patients with uncontrolled hypertension and with concomitant use of CYP2C8 inhibitors. Jesduvroq has labeled warnings and precautions for the risk of hospitalization for heart failure, hypertension, gastrointestinal erosion, malignancy, and is not indicated for patients who are not dependent on dialysis. Jesduvroq is associated with several drug-drug interactions. Reduce the starting dose of Jesduvroq if concomitantly used with moderate CYP2C8 inhibitors and monitor hemoglobin and adjust dosage as needed if concomitantly used with CY2C8 inducers. The starting dose of Jesduvroq should be reduced in patients with mild to moderate hepatic impairment. The use of Jesduvroq is not recommended in patients with severe hepatic impairment. The most common adverse reactions (≥10%) reported with Jesduvroq are hypertension, thrombotic vascular events, and abdominal pain.

Lamzede (velmanase alfa-tycv)

Indication: Non-central nervous system manifestations of alpha-mannosidosis

Mechanism of Action: Recombinant human lysosomal alpha-mannosidase

Dosage Form(s): Intravenous injection

Comments: Lamzede is FDA-approved for treating adults and pediatrics with non-central nervous system manifestations of alpha-mannosidosis. Prior to the initiation of Lamzede, consider pretreatment with antihistamines, antipyretics, and/or corticosteroids as well as verifying that females of reproductive potential are not pregnant. The recommended dose of Lamzede is 1mg/kg (actual body weight) administered over a minimum of 60 minutes once weekly as an intravenous infusion. Lamzede has specific instructions for reconstitution and storage, see full prescribing information for complete details. Lamzede has a boxed warning for severe hypersensitivity reactions (including anaphylaxis). If a hypersensitivity reaction occurs, Lamzede should be discontinued immediately, and appropriate medical support treatment should be initiated. Lamzede has labeled warnings and precautions for infusion-associated reactions and embryo-fetal toxicity. The most common adverse reactions (≥20%) reported with Lamzede area anaphylaxis, nasopharyngitis, pyrexia, headache, and arthralgia.

Current Drug Shortages

The following shortages have been recently identified or updated by the FDA:

- Amphetamine and dextroamphetamine salts
- Clonazepam tablets
- Methotrexate injection

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

Skyclarys (omaveloxolone)

Indication: Friedreich's ataxia

Mechanism of Action: Activation of the nuclear factor (erythroid-derived 2)-like 2 pathway (Nrf2); however, the exact mechanism is unknown

Dosage Form(s): Oral Capsules

Comments: Skyclarys is FDA-approved for treating Friedrich's ataxia in patients ≥16 years old. The recommended dose of Skyclarys is 150mg taken orally once daily. Skyclarys capsules should be swallowed whole and on an empty stomach ≥1 hour prior to eating. Capsules should not be opened, crushed, or chewed. The following labs should be obtained prior to and during treatment with Skyclarys: aminotransferases (AST/ALT), bilirubin B-type natriuretic peptide (BNP), and lipid monitoring parameters. Reduce the dose of Skyclarys to 100mg once daily for patients with moderate hepatic impairment and can be further reduced to 50mg once daily if adverse reactions occur. Use of Skyclarys should be avoided in patients with severe hepatic impairment. Skyclarys has labeled warnings and precautions for the elevation of aminotransferases, BNP, and lipid abnormalities. Aminotransferases should be monitored every month for the first 3 months and periodically thereafter. Patients should also be advised to monitor for signs and symptoms of fluid overload if elevation of BNP occurs. The periodic monitoring of cholesterol during treatment should also occur. Skyclarys should not be concomitantly used with moderate or strong CYP3A4 inhibitors or inducers; however, if the use is unavoidable with CYP3A4 inhibitors a dosage reduction along with monitoring of Skyclarys is recommended. The most common reactions (≥20%) reported with Skyclarys are elevated AST/ALT, headache, nausea, abdominal pain, fatigue, diarrhea, and musculoskeletal pain.

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, or Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Syfovre (pegcetacoplan)	Geographic atrophy secondary to age-related macular degeneration	Complement inhibitor	Intravitreal injection	New dosage form
Atorvaliq (atorvastatin calcium)	Primary familial hypercholesterolemia	HMG-CoA reductase inhibitor	Oral suspension	New dosage form